



January 11, 2016

Pharmaceutical Working Group  
c/o Angelo J. Bellomo, REHS, QEP  
Deputy Director for Health Protection  
5050 Commerce Drive  
Baldwin Park, CA 91706

**RE: Pharmaceuticals and Sharps Collection and Disposal Stewardship Ordinance (OPPOSE)**

Dear Mr. Bellomo:

On behalf of the Biotechnology Innovation Organization (“BIO”), the world’s largest trade association representing biotechnology companies, academic institutions, state biotechnology centers, and related organizations; I write to oppose the Pharmaceuticals and Sharps Collection and Disposal Stewardship Ordinance. This measure would require manufacturers of certain drugs and medical sharps to design, implement, and pay for a drug and sharps stewardship program in Los Angeles County. While we appreciate the goal of reducing illicit diversion of prescription drugs, safeguarding our waterways from contamination, and preventing accidental needlestick injuries – this approach would mandate an expensive and burdensome new program for disposal on a single stakeholder, and there is no evidence suggesting a stewardship program is a better option for drug and sharps disposal versus household trash.

**Existing Disposal Methods for Unwanted Drugs Are Safer and More Environmentally Sound**

Proponents of drug stewardship programs tout the benefits to the environment and public safety, but there is no evidence that stewardship programs have any effect on water quality, reducing prescription drug abuse, or preventing needlestick injuries. In fact, there is significant evidence that the current approach recommended by the FDA and EPA – household trash disposal – is the most preferable option for the environment and to reduce the risk of illicit diversion. Consider the following:

- Household trash disposal is the fastest method of removing drugs that have the potential for abuse from the home. Participation in a stewardship program encourages stockpiling and increases the number of people with access to the product before it is ultimately disposed. By mixing unwanted drugs with water and an undesirable substance, such as kitty litter or coffee grounds, they begin to degrade and are less likely to be abused even if they are discovered before collected by a waste hauler.
- Trace amounts of active pharmaceutical ingredients currently found in waterways are miniscule and the result of human excretion – not flushing medications or household

trash disposal. In fact, the past four annual reports from the British Columbia takeback program state, “The bulk of human pharmaceuticals found in waterways most likely got there by way of sewage. It is questioned whether take-backs have any real environmental and safety benefit.”<sup>1</sup>

- The amount of active pharmaceutical ingredients found in waterways is infinitesimally small – measuring in just a few parts per trillion, or one eyedropper’s amount diluted in 20 Olympic swimming pools. Former Greenpeace leader Patrick Moore concluded that drug disposal programs are “unneeded” as a result in a January 4, 2011 op-ed to the San Francisco Chronicle
- Stewardship programs have been in place for unused medicines in Europe for more than a decade, and studies examining various water samples in countries with mandatory drug disposal programs have not shown any measurable changes in the concentration of pharmaceuticals in surface waters after the enactment of drug stewardship programs (Ternes 1998; Wick et al. 2009; Coetsier et al. 2009).
- Other studies have examined the environmental impact of unused drugs that were disposed in landfills. In 2006, Tischler and Kocurek studied the potential for release of 23 APIs to surface waters through disposal in Subtitle D municipal solid waste (MSW) landfills. The potential landfill releases were compared to the releases occurring from patient use and excretion to wastewater treatment systems. Despite several conservative estimates designed to over-predict the occurrence and release of APIs in landfill leachate, the authors found that the average contribution of landfill leachate to the total load of APIs in surface water ranged from 0.21% to 0.78%. In other words, only a fraction of one percent of all APIs discharged to surface waters was estimated to originate from drugs disposed in landfills.
- Finally, drug stewardship programs have demonstrable environmental impacts that potentially outweigh any benefits imagined by the proponents. All drugs collected by a stewardship program would need to be repackaged and transported across state lines to one of two approved incineration facilities for medical waste (the waste from Alameda County’s program currently goes to Kansas City, Missouri.) As a result, the negative impacts to air quality will far exceed any positive impacts to water quality.

### **Medical Sharps Have a Unique Set of Parameters That the County Has Not Considered**

Medical sharps are unique from drugs in various ways, and the County has not taken these differences into consideration in the drafting of this ordinance. The manufacturers of sharps are largely a different set of companies than those that manufacture drugs; the collection of sharps is inherently more difficult than the collection of drugs; and the various existing programs that exist for sharps collection that our member companies participate in have been ignored in this exercise.

- Various new technologies have come to market in the past decade in light of safety concerns with home generated medical sharps waste. These technologies destroy the sharp or provide an automatic cover that renders the sharp inert. Companies that offer

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<sup>1</sup> Health Product Stewardship Association Annual Report, “Annual Report to the Director 2012,” p 11.

these products should be exempt from participating in a takeback ordinance given that they have provided a workable, market-based solution for the stated problem.

- This measure will have an extremely miniscule impact at a great cost. In 2014, the legislature considered a bill that would have required the sale of an approved, labeled sharps disposal container with the sale of medical sharps for injection (AB 1893). During the debate, the California Department of Industrial Relations testified that community acquired needlestick injuries (CANSI), which includes any needlestick injury outside of the healthcare setting, is less than on-half of one-percent of reported injuries. National data indicates similar low risk from CANSI.
- There is significant concern among our industry that various other entities will utilize sharps collection to dispose of waste generated in for-profit businesses, such as tattoo parlors and retail pharmacies; as well as waste from needle exchange programs. Studies from Canadian provinces that have sharps collection suggest that a significant portion of the waste collected was not the result of legally prescribed, in-home administration of pharmaceuticals.
- The Los Angeles approach to product stewardship involves an unprecedented co-mingling of drugs and sharps, both of which have unique disposal challenges. This has not been attempted anywhere else. While Alameda and Santa Cruz Counties have recently passed takeback legislation that includes sharps, the sharps component has yet to be implemented. None of the Canadian provinces that have takeback programs mix drugs and sharps in takeback receptacles. This will complicate waste destruction, increase cost, and expand the number of workers who have to handle medical waste.

#### **Shared Responsibility Among All Stakeholders Is Absent In This Approach**

The drug stewardship program contemplated in this bill would be expensive to implement, difficult to administer logistically, and could increase costs to the health care system all while providing little if any discernible benefit.

- The pharmaceutical supply chain in the United States is complex, and includes manufacturers, wholesalers, doctors, hospitals, nursing facilities, insurance companies, government programs like Medicare and Medicaid, retail pharmacies, and finally patients. To charge full freight to the manufacturers for drug disposal is inherently inequitable, enacts a complex web of regulation without any input or participation from the majority of stakeholders, and will lead to a program that is unworkable.
- Retail pharmacies have been granted wholesale exemptions from participating in the drug stewardship programs enacted in California thus far, even though retail takeback kiosks are explicitly listed as the central feature of these programs. At a very minimum, retail pharmacies should be required to participate should the county approve a stewardship plan that includes retail pharmacy kiosks. While not every retail pharmacy would be an ideal location for takeback, many will be and retail pharmacies should actively participate in the design of any stewardship program and host kiosks where appropriate. This participation cannot be voluntary if we hope to have broad participation by pharmacies, making the kiosks accessible and the program successful.

- Our industry has no authority to compel retailers to participate if not required in statute. DEA regulations<sup>2</sup> published late last year require private entities that participate in drug stewardship programs to register as “collectors” with the DEA and keep accurate records of the drugs collected, including their transfer to a registered waste hauler. Failure to do so can result in fines, and it is unlikely that a for-profit company would assume this liability unless they are required to do so.

### **The County Should Demonstrate That the Program Achieves Its Goals**

Los Angeles County has an appropriate role to play in demonstrating that the stated goals of this legislation are being achieved.

- As the County is requiring a private industry to design, implement, and pay for a public program – over the strong and universal objection of the affected industry – it should at a minimum evaluate the program to ensure that it is meeting the stated goals of improving water quality and reducing the incidence of prescription drug abuse. In our experience with these programs in other jurisdictions, they are ineffective, environmentally unsound, and difficult for patients to comply. If the County cannot demonstrate in a quantifiable way that the stewardship program positively impacts the problems it seeks to resolve, the program should be discontinued.

For the above stated reasons, BIO is opposed to the proposed Pharmaceuticals and Sharps Collection and Disposal Stewardship Ordinance in Los Angeles County. We remain committed to improving awareness of effective, FDA-approved disposal methods through targeted education in Los Angeles. We welcome the opportunity to discuss our thoughts on this matter with you. Should you have any questions or concerns, please contact Ritchard Engelhardt at [rengelhardt@bio.org](mailto:rengelhardt@bio.org) or (212) 335-0385.

Sincerely,



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State Director of Government Affairs  
Northeastern and Western Regions

Cc: Supervisor Michael D. Antonovich  
Supervisor Don Knabe  
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<sup>2</sup> Federal Register, Vol. 79, Issue 174. <http://www.gpo.gov/fdsys/granule/FR-2014-09-09/2014-20926>